



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Docket No. 400140)

RECEIVED

MAY 26 2004

TECHNOLOGY CENTER R3700

DECLARATION UNDER 37 C.F.R. SECTION 1.131

I, Donald K. Jones, declare as follows:

1. I am a co-inventor of the invention disclosed and claimed in the above identified application.
2. I have a degree in material science and engineering. I have worked in the field of biomedical engineering, including embolization devices, for over seven years. I am an inventor in numerous patents relating to neurological devices.

3. It is my understand that U.S. Patent No. 6,280,457 to Wallace et al., filed June 4, 1999, has been cited by the Patent and Trademark Office in support of rejections of claims 1-4, 6-14, 16, 17, 20, and 27 of the above-identified application.

4. The invention of this application was made prior to June 4, 1999, the date of filing of U.S. Patent No. 6, 280,457. More specifically, the invention was made and completed, and actually reduced to practice, all in the United States of America, prior to June 4, 1999, as evidenced by the attached exhibits.

5. Exhibit A is a date-redacted copy of an invention record disclosure signed by Vladimir Mitelberg and me. Exhibit A reports on work performed by us and/or under our direction and control in the United States of America prior to June 4, 1999, in connection with making embolic coils for occluding the vasculature of a patient, which devices were made and reduced to practice before June 4, 1999.

6. With respect to Exhibit A (the invention record) referred to in paragraph 5 above, the photographs set forth in the last page of this invention record were taken by me of the roughened coils prior to submitting them for evaluation. The page having the number 028122 shows service requests. The picture on the bottom is a service request in which the coils were submitted for evaluation. Four photomicrographs were taken as indicated by the middle box and these four microphotographs were the results of the service requests. These photomicrographs are on the page of Exhibit A following the service requests. All of these photographs and service requests were taken and made prior to June 4, 1999.

7. Exhibit B are date-redacted copies of experiments performed on baboons, in connection with occluding the vasculature of the baboons, which experiments were performed before June 4, 1999.

8. The work referred in paragraph 7 above, included ex-vivo tests outside of the body using the baboon. A silicone tube was connected to the artery of the baboon. Blood flow was through the silicone tube and back to the baboon. In the silicone tube, aneurysms were formed on the tube itself. A delivery catheter was used to place roughened embolic coils inside of the aneurysms, with the help of a pusher mechanism. Live blood was run through the system and radioactive platelets accumulated on the

coils. The coils used were textured 5 mm. complex coils. By using a gamma camera imager, the radioactivity was measured. Non-textured coils were also used. It was found that there were greater amount of platelets on the roughened coils then on the non-roughened coils. From these experiments we were able to conclude that the introduction of the textured coils in the aneurysm would enhance platelet adhesion.

9. In view of my experience in biomedical engineering (including embolization devices) prior to June 4, 1999, I was confident that the vasculature of a patient could be successfully occluded by providing a plurality of embolic coils having a proximal portion that is held by the detachment portion and a distal portion, with the proximal portion that is held by the detachment portion being relatively smooth and the distal portion having a relatively textured surface. I found that the textured surface provides improved platelet adhesion compared to a non-textured surface, to promote clotting. As a result of the experiments, I was confident that the embolization device having a roughened surface was suitable for placement in a catheter for being conventionally implanted with an introducer having a detachment portion to provide improved platelet adhesion compared to a non-textured surface, to promote clotting. Accordingly, in my view, the invention was reduced to practice on a date prior to June 4, 1999, because I was confident that clinical versions of the prototype could be sterilized and clinically used with success to embolize aneurysms in patients.

10. I hereby declare that all statements made herein and of my own knowledge are true, and that all statements made on information and belief are believed to be true; and I further declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or

imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and
that such willful false statements may jeopardize the validity of the application or patent
issued therefrom.

Date: 5/11/04


Donald K. Jones

Cordis

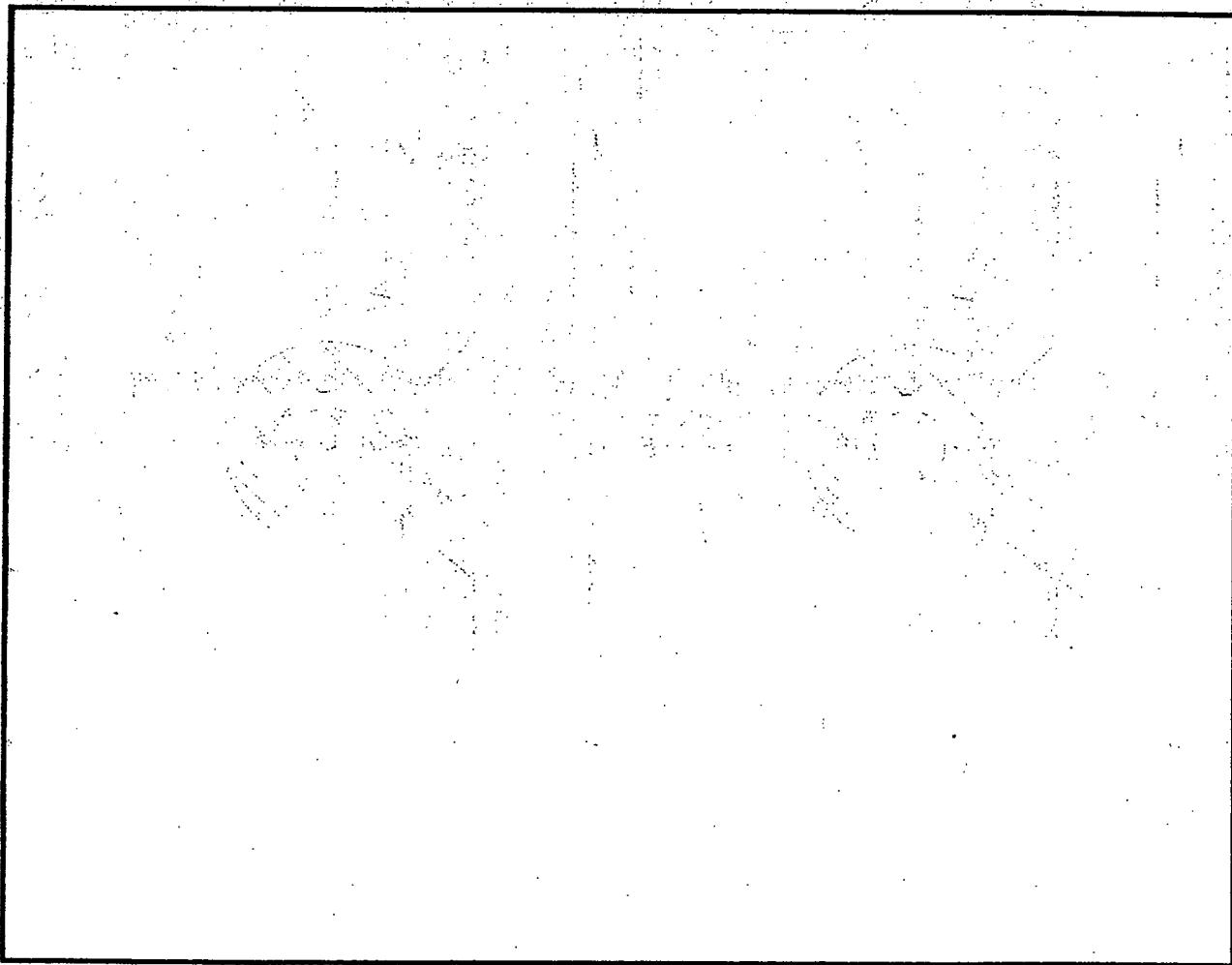
DEPARTMENT

00/40

Engineering Department

DESCRIPTIVE TITLE: Coil Surface Modification

- I. **INSTRUCTIONS:** This form should be typed, except for the signatures and dates. Disclose only one invention on this Invention Disclosure form, and complete the entire form as fully as possible. Forward the completed form to the Legal Department, signed and dated by all inventors and two witnesses. Refer to this Invention Disclosure by the number assigned to it when receipt is acknowledged. Attach additional sheets if more space is required. Each original piece of paper must be signed and dated by every inventor and by each witness.
- II. **ILLUSTRATION:** *Include a drawing, sketch, photograph, flow chart, or preferably an engineering quality printout of the invention.*



Name & Signature of Inventor(s):

Date

Witnesses

Date

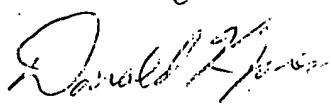
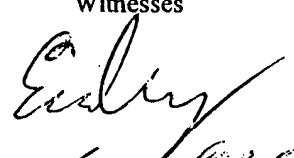
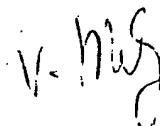


EXHIBIT A

DEPARTMENT

III. EXPLANATION OF INVENTION: *Describe the invention completely, including all essential elements.*

The invention is a surface modified embolization coil. The surface has been textured by abrasion or "sand blasting". Fifty-micron diameter alumina particles were used to texture the surface of the platinum tungsten wire used to form the coils. It is believed that the textured surface provides improved platelet adhesion thus promoting clotting and subsequent endothelialization. SEM micrographs and optical pictures of the textured vs. non-textured are attached. Testing using radiolabeled platelets was conducted to evaluate an ex vivo aneurysm model. In the model, aneurysms treated with textured coils were compared to aneurysms treated with non-textured coils. The textured coils showed an increase in the platelet deposition of about 50% over the non-textured coils.

IV. NOVEL FEATURES AND ADVANTAGES: *What is new that was not previously known, and why is this important.*

Other surface modification techniques such as coating or ion implantation require expensive and elaborate equipment to modify the coils which add an additional component. This method does not impart any new materials to the coil that would require new biocompatibility testing and can be done inexpensively.

V. MODIFICATIONS: *Describe all possible modifications or alternate embodiments.*VI. RELATED DOCUMENTS: *List all known relevant art references (patents, publications, commercially available products, etc.). Please supply copies of the documents, if available.*

Patents:

Publications:

Signature of Inventor(s):

Date:

Witnesses:

Date:

V. Muf
Donald K. Green

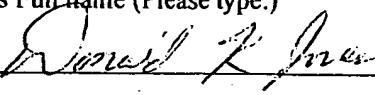
Eddy
John

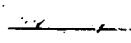
VII. INVENTORS:

DEPARTMENT

First Inventor's Full name (Please type):

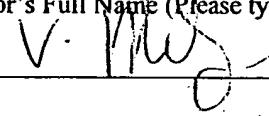
Donald K. Jones

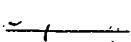
Signature: 

Date: 

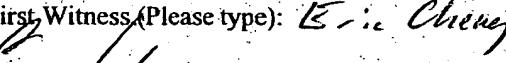
Second Inventor's Full Name (Please type):

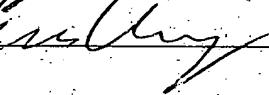
Vladimir Mitelberg

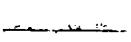
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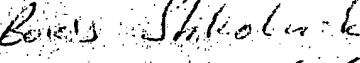
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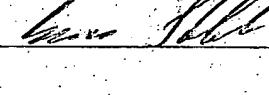
VIII. WITNESSES: This invention was disclosed to and understood by:

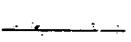
Full Name of First Witness (Please type): 

Signature: 

Date: 

Full Name of Second Witness (Please type): 

Signature: 

Date: 

IX. ADDITIONAL INFORMATION:

Invention is recorded on page(s): _____ of Notebook No.: _____ dated: _____

Earliest date: _____ and place: CES where inventors first thought of the present invention.

First written description (date and present location): _____

First sketch of the invention (date and present location): _____

Earliest date: _____ and place: _____ where first operating model was completed.

Present location of model: _____

Earliest date of use of the invention (actual or contemplated): _____

Earliest shipping date (actual or contemplated): _____

Service Request

Job number, assigned by
supplying organization

32027

Requestor	To	CPQT, ETL, LNS	Project/Charge
	From (organization)	CES	Date required
	Location	ETER SITUANCES x 8620	
	For information contact		
	Description of request	Please provide SEPI photos of surface of cores provided for roughness evaluation.	
Requested by	J. R. Alvarado	Date	
Approved by		Date	

Supplier	Date received	
	Labor cost	
	Material cost	
	Purchased Materials, services or equipment required	notebook 92071-46
	Completion date	
Comments	Electron optical micrographs were taken of each sample at low & high magnifications to show surface roughness conditions.	
Estimate by	J. R. Alvarado John Dahl	Date

Approval	Cost and completion date accepted by requestor	
	Signature	Date
	Comment	
	John Dahl	
	Supplier acceptance by	Date

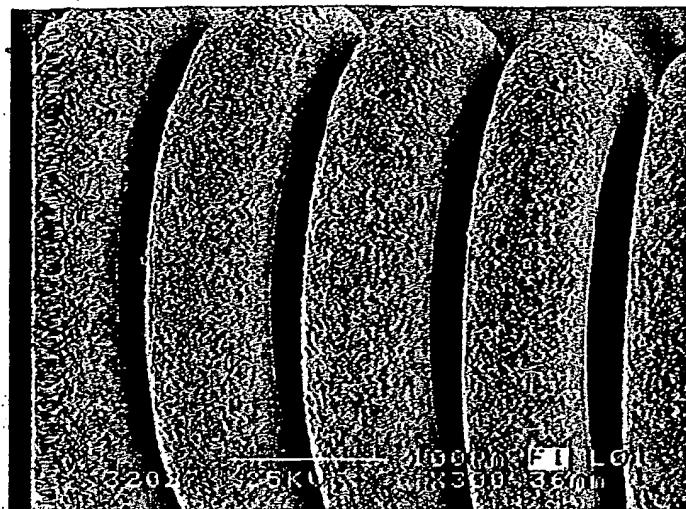


Figure 1-(233x) Sample with rough surface

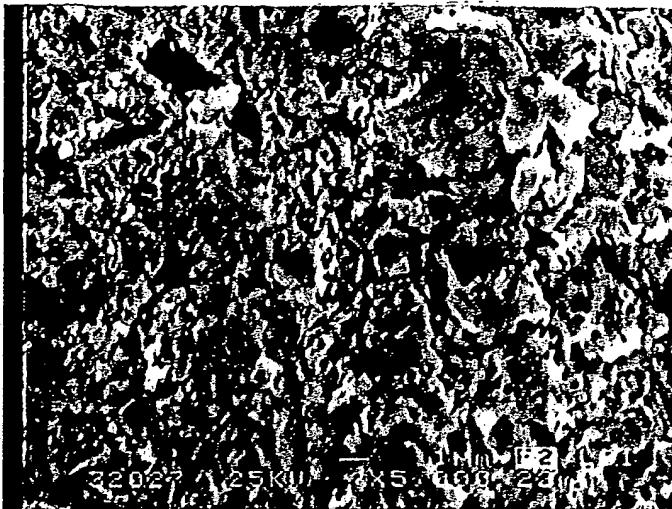


Figure 2-(3880x) Sample with rough surface

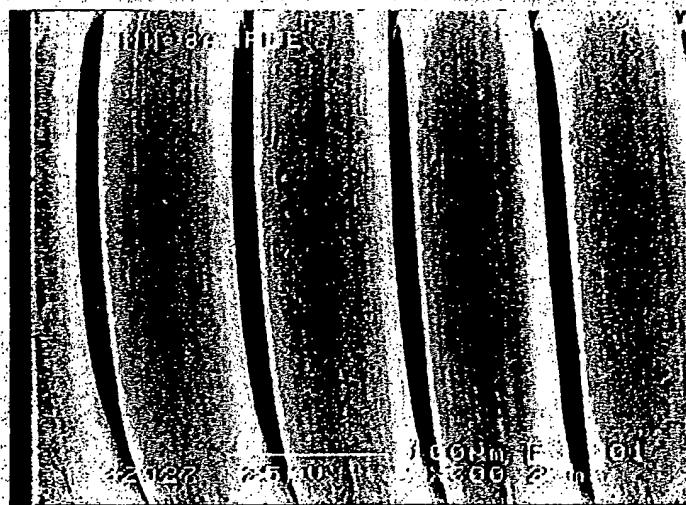


Figure 3-(233x) Sample "MW" with smooth surface.

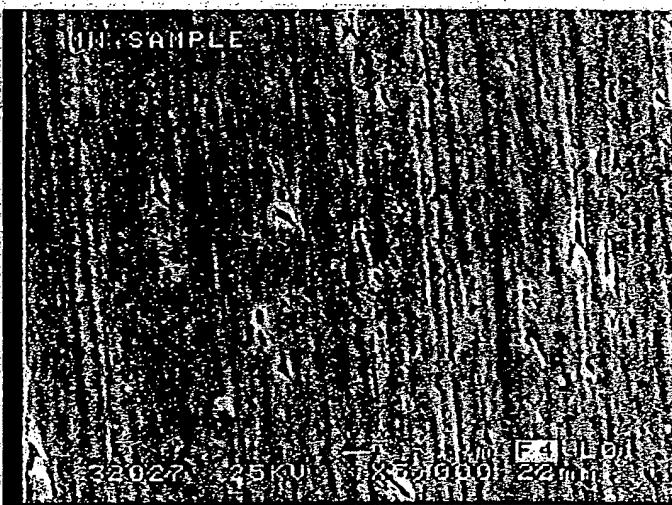


Figure 4-(3880x) Sample "MW" with smooth surface.

W. W. H. 11/11/91

40 X mag

.003" Hg

5nm
Complex
(20- μ long)

No Surface Treatment



114

PAT

DEPAI

DKP

40 X mag

.003" Hg

5nm
Complex
(20- μ long)

Surface Treatment



115
Comparing Surface

Surface Abraded Using AcuBRADe - 5 30nm³
50 micron blend of Al₂O₃ (Part No. 4P805)

DKP

Baboon B384 right

Date	Computer	Data Partition	Pit Cnt Pre	314	Whole Blood	171188
	A3	GE	Pit Cnt Post	267	Plasma	21908
	Camera		WBC	8.7	Fraction	92.5%
Study Description	ROI (device)	8 x 10	Hct Pre	41.10%	Free	7.5%
Aneurysm Run #7 textured 5mm dlm..complex coils. Tail from Aneur. #1 extended 130mm. Tail from Aneur. #2 extended 180mm	Window	15%	Hct Post	38.00%	Volume (cc)	3
iodine	Energy	> 172	Flow (ml/min)	100 clamp		
Remarks	Collimator	> low med word	Blood Std CPM	2285		
	Matrix	> byte	Bkg CPM	291		
			Bkgd CPM	11994		
			CPM In-pits	1843 688		
			CPM/ml In-pits	614.5654		
			FINIAL	0.000511		

#	ROI	ROI	Time	Time	ROI	Time	Time	ROI	Time
Min	CPM	CPM	Min	CPM	CPM	Min	CPM	CPM	Min
5	196	167	29	0.000511	0.01	165	1800	1250	550.00
10	197	166.00	31	0.000511	0.02	160	1800	1400	400.00
15	285	266.00	19	0.000511	0.01	165	1700	1260	440.00
20	356	428.00	-72	0.000511	-0.04	170	1600	1250	350.00
25	609	845.00	-38	0.000511	-0.02	175	1770	1270	500.00
30	870	849.00	-21	0.000511	0.01	180	1650	1250	400.00
35	1100	1140.00	-40	0.000511	-0.02	185	1640	1270	370.00
40	1340	1430.00	-90	0.000511	-0.05	190	1730	1230	500.00
45	1540	1570.00	-72	0.000511	-0.04	195	1740	1240	500.00
50	1840	1810.00	-30	0.000511	0.02	200	1620	1270	350.00
55	2020	1860.00	-170	0.000511	0.09	205	1630	1230	400.00
60	2130	1940.00	-190	0.000511	0.10	210	1720	1210	510.00
65	2220	2080.00	-140	0.000511	0.07	215	1650	1230	420.00
70	2170	1960.00	-210	0.000511	0.11	220	1690	1250	440.00
75	1990	1890.00	-100	0.000511	0.05	225	1640	1120	520.00
80	1950	1750.00	-200	0.000511	-0.10	230	1680	1160	420.00
85	1790	1730.00	-60	0.000511	0.03	235	1720	1150	570.00
90	1730	1650.00	-180	0.000511	0.09	240	1520	1080	440.00
95	1750	1670.00	-80	0.000511	0.04				
100	1780	1610.00	-170	0.000511	-0.09				
105	1730	1600.00	-130	0.000511	-0.07				
110	1730	1540.00	-190	0.000511	0.10				
115	1680	1460.00	-220	0.000511	0.11				
120	1710	1470.00	-240	0.000511	0.12				
125	1700	1470.00	-230	0.000511	0.12				
130	1750	1310	-380	0.000511	0.19				
135	1720	1440	-280	0.000511	0.14				
140	1740	1480	-280	0.000511	0.14				
145	1850	1310	-540	0.000511	0.28				
150	1730	1390	-340	0.000511	0.17				

Baboon B384 right
 Date
 Study Description
Aneurysm Run #7 textured 5mm dim. complex
 coils. Tail from Aneu. #1 extended 130mm.
 Tail from Aneu.#2 extended 180mm
 Iodine
 Remarks

#2	ROI	ROI	Time	CPM	CPM	CPM	bkg	Thrombus	Standard	Pits x10 ³
5	216	169	6	47.00	0.000511	0.02				
10	255	224.00	10	31.00	0.000511	0.02				
15	267	255.00	15	12.00	0.000511	0.01				
20	428	341.00	20	87.00	0.000511	0.04				
25	551	431.00	25	120.00	0.000511	0.08				
30	665	583.00	30	82.00	0.000511	0.04				
35	902	798.00	35	104.00	0.000511	0.05				
40	1020	792.00	40	228.00	0.000511	0.12				
45	1170	892.00	45	67.00	0.000511	0.04				
50	1260	929.00	50	331.00	0.000511	0.17				
55	1300	947.00	55	353.00	0.000511	0.18				
60	1330	984.00	60	366.00	0.000511	0.19				
65	1380	998.00	65	362.00	0.000511	0.18				
70	1440	998.00	70	442.00	0.000511	0.23				
75	1510	985.00	75	525.00	0.000511	0.27				
80	1540	1020.00	80	520.00	0.000511	0.27				
85	1740	1100.00	85	640.00	0.000511	0.33				
90	1620	1040.00	90	580.00	0.000511	0.30				
95	1540	1000.00	95	540.00	0.000511	0.28				
100	1490	1050.00	100	440.00	0.000511	0.22				
105	1600	998.00	105	612.00	0.000511	0.31				
110	1600	892.00	110	708.00	0.000511	0.36				
115	1600	988.00	115	644.00	0.000511	0.33				
120	1680	903.00	120	777.00	0.000511	0.40				
125	1650	934.00	125	696.00	0.000511	0.36				
130	1680	892.00	130	788.00	0.000511	0.40				
135	1680	860	135	820.00	0.000511	0.42				
140	1770	806	140	964.00	0.000511	0.49				
145	1740	790	145	950.00	0.000511	0.49				
150	1700	844	150	856.00	0.000511	0.44				

#2	ROI	ROI	Time	CPM	CPM	CPM	bkg	Thrombus	Standard	Pits x10 ³
5	216	169	6	47.00	0.000511	0.02				
10	255	224.00	10	31.00	0.000511	0.02				
15	267	255.00	15	12.00	0.000511	0.01				
20	428	341.00	20	87.00	0.000511	0.04				
25	551	431.00	25	120.00	0.000511	0.08				
30	665	583.00	30	82.00	0.000511	0.04				
35	902	798.00	35	104.00	0.000511	0.05				
40	1020	792.00	40	228.00	0.000511	0.12				
45	1170	892.00	45	67.00	0.000511	0.04				
50	1260	929.00	50	331.00	0.000511	0.17				
55	1300	947.00	55	353.00	0.000511	0.18				
60	1330	984.00	60	366.00	0.000511	0.19				
65	1380	998.00	65	362.00	0.000511	0.18				
70	1440	998.00	70	442.00	0.000511	0.23				
75	1510	985.00	75	525.00	0.000511	0.27				
80	1540	1020.00	80	520.00	0.000511	0.27				
85	1740	1100.00	85	640.00	0.000511	0.33				
90	1620	1040.00	90	580.00	0.000511	0.30				
95	1540	1000.00	95	540.00	0.000511	0.28				
100	1490	1050.00	100	440.00	0.000511	0.22				
105	1600	998.00	105	612.00	0.000511	0.31				
110	1600	892.00	110	708.00	0.000511	0.36				
115	1600	988.00	115	644.00	0.000511	0.33				
120	1680	903.00	120	777.00	0.000511	0.40				
125	1650	934.00	125	696.00	0.000511	0.36				
130	1680	892.00	130	788.00	0.000511	0.40				
135	1680	860	135	820.00	0.000511	0.42				
140	1770	806	140	964.00	0.000511	0.49				
145	1740	790	145	950.00	0.000511	0.49				
150	1700	844	150	856.00	0.000511	0.44				

Baboon 37/41ptt.

Date

Computer

Data Partition

Camera

ROI (device)

8 x 10

A3

A341

GE

WBC

11.5

Hct Pre

45.40%

Hct Post

42.10%

Flow (ml/min)

100/clamp

> 247

Window

> 172

Energy

> 128

Matrix

> 8

Collimator

> 4

med

word

word

bit

Whole Blood 121465

Plasma 16014

Fraction 92.8%

Free 7.2%

ROI	ROI	ROI	ROI	ROI	ROI	ROI	ROI
16x72	16x66	CPM	Time	155	510	206	304.00
Min.	CPM	CPM bkg	Thrombus	0.000689	0.02	0.000689	0.21
5	184	150	34.00	0.000689	0.02	0.000689	0.23
10	190	168	22.00	0.000689	0.02	0.000689	0.23
15	215	240	-25.00	0.000689	0.02	0.000689	0.23
20	324	303	21.00	0.000689	0.01	0.000689	0.23
25	493	442	51.00	0.000689	0.04	0.000689	0.26
30	592	538	54.00	0.000689	0.04	0.000689	0.23
35	751	641	110.00	0.000689	0.08	0.000689	0.26
40	866	716	150.00	0.000689	0.10	0.000689	0.24
45	991	848	21.00	0.000689	0.01	0.000689	0.24
50	1120	918	202.00	0.000689	0.14	0.000689	0.34
55	1280	1050	230.00	0.000689	0.16	0.000689	0.28
60	1390	1050	340.00	0.000689	0.23	0.000689	0.27
65	1650	1180	470.00	0.000689	0.32	0.000689	0.28
70	1650	1250	400.00	0.000689	0.28	0.000689	0.26
75	1570	1210	360.00	0.000689	0.25	0.000689	0.30
80	1480	1200	280.00	0.000689	0.19	0.000689	0.23
85	1470	1140	330.00	0.000689	0.23	0.000689	0.24
90	1660	718	942.00	0.000689	0.85	0.000689	0.33
95	1790	458	1332.00	0.000689	0.92	0.000689	0.00
100	1750	466	1284.00	0.000689	0.88	0.000689	0.00
105	1760	434	1326.00	0.000689	0.91	0.000689	0.00
110	1830	460	1370.00	0.000689	0.84	0.000689	0.00
115	1810	466	1344.00	0.000689	0.83	0.000689	0.00
120	1510	380	1130.00	0.000689	0.78	0.000689	0.00
125	276	113	163.00	0.000689	0.11	0.000689	0.00
130	300	130	170.00	0.000689	0.12	0.000689	0.00
135	378	154	224.00	0.000689	0.15	0.000689	0.00
140	420	158	284.00	0.000689	0.18	0.000689	0.00
145	486	166	320.00	0.000689	0.22	0.000689	0.00
150	510	190	320.00	0.000689	0.22	0.000689	0.00

Aneurysm Run #1 untextured 5mm diam. complex

colls. Tail from Aneu. #1 stopped 1.25" from aneu.

#2. Tail from Aneu. #2 extended 16"

flow stopped at Thr 25min - shunt was flushed

Remarks

ROI (device)

8 x 10

A3

A341

GE

WBC

11.5

Hct Pre

45.40%

Hct Post

42.10%

Flow (ml/min)

100/clamp

> 247

Window

> 172

Energy

> 128

Matrix

> 8

Collimator

> 4

med

word

word

bit

ROI (device)

A3

A341

GE

WBC

11.5

Hct Pre

45.40%

Hct Post

42.10%

Flow (ml/min)

100/clamp

> 247

Window

> 172

Energy

> 128

Matrix

> 8

Collimator

> 4

med

word

word

bit

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